

3TC[®]

Patient Information Leaflet

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND DOSAGE FORM:

3TC[®] TABLETS (lamivudine 150 mg/tablet)

3TC[®] ORAL SOLUTION (lamivudine 10 mg/ml oral solution)

Please read all of this leaflet carefully before you start taking 3TC.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- 3TC has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT 3TC CONTAINS:

The active substance in 3TC is lamivudine.

3TC TABLETS:

Each tablet contains 150 mg of the active ingredient lamivudine.

The other ingredients are: Tablet core: magnesium stearate, microcrystalline cellulose and sodium starch glycollate. Film-coating: hydroxypropylmethyl cellulose, macrogol, polysorbate 80 and titanium dioxide.

3TC ORAL SOLUTION:

Each ml of solution contains 10 mg of the active ingredient lamivudine.

Contains sugar (sucrose 20 % *m/v*).

The other ingredients are: artificial banana flavour, artificial strawberry flavour, citric acid anhydrous, methyl hydroxybenzoate (0,15 % *m/v*), propyl hydroxybenzoate (0,018 % *m/v*), propylene glycol, purified water, sodium citrate.

WHAT 3TC IS USED FOR:

3TC belongs to a group of antiviral medicines, also known as antiretrovirals, called nucleoside analogue reverse transcriptase inhibitors (NRTIs).

These are used to treat human immunodeficiency virus (HIV) infection, which can lead to acquired immunodeficiency syndrome (AIDS).

3TC is used in antiretroviral combination therapy for the treatment of HIV infection in children and adults.

3TC does not cure AIDS or kill HIV but helps to prevent further damage to the immune system by slowing production of new viruses.

BEFORE YOU TAKE 3TC:**Do not take 3TC:**

- if you are allergic (hypersensitive) to lamivudine or to any of the ingredients of 3TC.

Check with your doctor if you think this applies to you.

Take special care with 3TC:

- if you have ever had liver disease, including hepatitis B or C
- if you have ever had kidney disease
- if you're diabetic and using insulin.

Talk to your doctor if any of these apply to you. Your doctor may need to adjust your dose, or you may need extra check-ups (including blood tests) while you're taking your medicine. See POSSIBLE SIDE EFFECTS.

3TC can cause a condition called lactic acidosis (excess of lactic acid in your blood), together with an enlarged liver. (See "Possible side effects of combination therapy for HIV" in POSSIBLE SIDE EFFECTS.)

Protect other people:

HIV infection is spread by sexual contact with someone who has the infection, or by transfer of infected blood (for example, by sharing injection needles). 3TC will not stop you passing HIV infection on to other people. To protect other people from becoming infected with HIV:

- Use a condom when you have sex (of any kind, including oral sex).
- Don't risk blood transfer – for example, don't share needles.

Taking 3TC with food or drink:

3TC can be taken with or without food.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Women who are HIV-positive should not breastfeed. This is because HIV infection can be passed on to the baby in breast milk.

Driving and using machinery:

Don't drive or use machinery until you know whether 3TC affects your ability to do so.

Important information about some of the ingredients of 3TC:

3TC ORAL SOLUTION contains sucrose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking 3TC ORAL SOLUTION. 3TC ORAL SOLUTION may have an effect on the control of your blood sugar if you have diabetes mellitus. Please note that each 150 mg dose (or 15 ml) contains 3 g of sucrose.

Taking other medicines with 3TC:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

These medicines should not be used with 3TC:

- Zalcitabine or emtricitabine, used to treat HIV infection.

Some medicines may affect how 3TC works or make it more likely that you'll have side effects. These medicines include:

- Trimethoprim-sulphamethoxazole (also known as co-trimoxazole), an antibiotic used to treat *Pneumocystis carinii* pneumonia or toxoplasmosis.

Tell your doctor or pharmacist if you are taking any of these.

HOW TO TAKE 3TC:

Do not share medicines prescribed for you with any other person.

Always take 3TC exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

3TC is always taken with zidovudine (AZT), please read the information given with zidovudine before you take 3TC. Please consult your doctor with regard to the zidovudine dosage.

How much to take:

Tablets:

Adults, adolescents and children weighing at least 25 kg:

The usual dose of 3TC TABLETS is:

- one 3TC tablet to be taken twice a day approximately 12 hours apart,

or

- two 3TC tablets taken together, once a day.

Children weighing at least 20 kg and less than 25 kg:

The usual dose of 3TC TABLETS is:

- one-half ($\frac{1}{2}$) 3TC tablet to be taken in the morning and one whole 3TC tablet to be taken in the evening,

or

- one and one-half (1 and $\frac{1}{2}$) 3TC tablets to be taken once daily.

Children weighing at least 14 and less than 20 kg:

The usual dose of 3TC TABLETS is:

- one-half ($\frac{1}{2}$) 3TC tablet, to be taken in the morning and one-half ($\frac{1}{2}$) 3TC tablet to be taken in the evening,

or

- one 3TC tablet, to be taken once daily.

3TC is also available as an oral solution.

Oral Solution:

Adults and children weighing at least 25 kg:

The usual dose of 3TC ORAL SOLUTION is:

either

- 15 ml to be taken twice daily,

or

- 30 ml to be taken once daily.

Children older than three months and weighing less than 25 kg:

Your doctor will decide on the correct dose of 3TC ORAL SOLUTION for your child, depending on their weight.

The usual dose of 3TC ORAL SOLUTION is:

- 4 mg/kg body weight twice daily up to a maximum of 30 ml daily,

or

- 8 mg/kg body weight once daily up to a maximum of 30 ml daily.

Patients with kidney problems:

If you have a kidney problem, your doctor may alter your dose.

Talk to your doctor if this applies to you.

How to take 3TC:

Tablets:

Swallow the tablets with some water. 3TC TABLETS can be taken with or without food.

If you cannot swallow the tablets whole, you may crush and combine them with a small amount of food and drink and take all the dose immediately.

Oral Solution:

3TC ORAL SOLUTION can be taken with or without food.

Use the oral dosing syringe supplied with the pack to measure your dose accurately.

1. Remove the bottle cap. Keep it safely.
2. Push the plastic adapter into the neck of the bottle, while holding the bottle firmly.
3. Insert the syringe firmly into the adapter.
4. Turn bottle upside down.
5. Pull out syringe plunger until the syringe contains the first part of your full dose.
6. Turn the bottle the correct way up and remove the syringe from the adapter.
7. Put the syringe into your mouth by placing the tip of the syringe against the inside of the cheek. Slowly push the plunger in, allowing time to swallow. Don't push too hard and squirt the liquid into the back of your throat as you may choke.
8. Repeat steps 3 to 7 in the same way until you have taken your whole dose.
9. Take the syringe out of the bottle and wash it thoroughly in clean water. Let it dry completely before you use it again.
10. Close the bottle tightly with the cap, leaving the adaptor in place.

If you take more 3TC than you should:

Accidentally taking too much 3TC is unlikely to cause any serious problems. In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take 3TC:

If you forget to take a dose, take it as soon as you remember. **Do not take a double dose** to make up for forgotten individual doses.

If you are not sure what to do, ask your doctor or pharmacist.

POSSIBLE SIDE EFFECTS:

3TC can have side effects.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, see a doctor immediately:

- rash
- a high temperature (*fever*)
- lack of energy (*fatigue*)
- joint pain, muscle disorders.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to 3TC. You may need urgent medical attention or hospitalisation.

Possible side effects of combination therapy for HIV

Combination therapy including 3TC may cause other conditions to develop during HIV treatment.

If any of the following happens, tell your doctor immediately. These are all very serious side effects.

Lactic acidosis is a rare but serious side effect

Some people taking 3TC or other medicines like it (NRTIs) develop a condition called lactic acidosis, together with an enlarged liver.

Lactic acidosis is caused by a build-up of lactic acid in the body. It is rare; if it happens it usually develops after a few months of treatment. It can be life-threatening, causing failure of internal organs.

Lactic acidosis is more likely to develop in people who have liver disease, or in very overweight (*obese*) people, especially women.

Signs of lactic acidosis include:

- deep, rapid, difficult breathing
- drowsiness
- numbness or weakness in the limbs
- feeling sick (*nausea*), being sick (*vomiting*)
- stomach pain.

During treatment your doctor will monitor you for signs of lactic acidosis. Tell your doctor as soon as possible if you have any of the symptoms listed above, or any other symptoms that worry you.

Old infections may flare up

People with advanced HIV infection (AIDS) have weak immune systems, and are more likely to develop serious infections (*opportunistic infections*). When these people start treatment, they may find that old, hidden infections flare up, causing signs and symptoms of inflammation. These symptoms are probably caused by the body's immune system becoming stronger, so that the body starts to fight these infections. If you get symptoms of infection while you're taking 3TC:

Tell your doctor immediately. Don't take other medicines for the infection without your doctor's advice.

Your body shape may change

People taking combination therapy for HIV may find that their body shape changes, because of changes in fat distribution:

- fat may be lost from the legs, arms or face.
- extra fat may build up around the tummy (*abdomen*), or on the breasts or internal organs.
- fatty lumps (sometimes called buffalo hump) may appear on the back of the neck.

It is not yet known what causes these changes, or whether they have any long-term effects on your health.

Tell your doctor if you notice any changes in your body shape.

Other effects may show up in blood tests

Combination therapy for HIV can also cause:

- **increased levels of lactic acid** in the blood, which can lead to lactic acidosis
- **increased levels of sugar and fats** (*triglycerides* and *cholesterol*) in the blood
- **resistance to insulin** so if you are diabetic, you may have to change your insulin dose to control your blood sugar.

Frequent side effects:

- headache
- generally feeling unwell (*malaise*)
- feeling sick (*nausea*), being sick (*vomiting*), diarrhoea
- stomach pain
- hair loss or thinning of hair (*alopecia*).

Side effects that may show up in your blood tests:

- an increase in a hormone called *prolactin* in the blood.

Less frequent side effects:

- lactic acidosis (see information in *Possible side effects of combination therapy for HIV*)

- changes in body shape (see information in *Possible side effects of combination therapy for HIV*)
- inflammation of the pancreas (*pancreatitis*)
- breakdown of muscle tissue
- tingling or numbness of the arms, legs, hands or feet.

Side effects that may show up in your blood tests:

- reduction in the number of white blood cells (*neutropenia*)
- reduction in the number of red blood cells (*anaemia*)
- reduction in the number of *platelets* (cells that make the blood clot) (*thrombocytopenia*)
- increase in liver enzymes
- an increase in the level of an enzyme called *amylase* in the blood
- a failure of the bone marrow to produce new red blood cells (*pure red cell aplasia*).

Tell your doctor or pharmacist if any of the side effects listed becomes **severe or troublesome**, or if you notice any side effects not listed in this leaflet.

STORAGE AND DISPOSING OF 3TC:

Store all medicines out of reach of children.

Do not take the tablets after the expiry date shown on the carton.

Store 3TC TABLETS at or below 30 °C.

Do not take the solution after the expiry date shown on the carton.

Store 3TC ORAL SOLUTION at or below 25 °C. Once opened, use the solution within one month.

Always return any unwanted medicine(s) to the doctor or pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION:

3TC TABLETS are supplied in cartons containing 60 tablets in a white high density polyethylene (HDPE) bottle, with a child-resistant cap.

3TC ORAL SOLUTION is supplied in cartons containing a white polyethylene bottle, with a child-resistant cap and dosing device. The bottle contains 240 ml (10 mg/ml) of lamivudine solution for oral use only.

IDENTIFICATION:

3TC TABLETS: White film-coated, diamond shaped scored tablets engraved 'GXCJ7' on both faces.

3TC ORAL SOLUTION: A clear, colourless to pale yellow solution with the odour of fruit.

REGISTRATION NUMBER:

3TC TABLETS: 30/20.2.8/0366

3TC ORAL SOLUTION: 30/20.2.8/0367

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:**Date of registration:**

3TC TABLETS: 13 June 1996

3TC ORAL SOLUTION: 13 June 1996

Date of most recent revision:

29 June 2018

GDS21